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Special 510(k): Device Modification -Summary

This Special 510(k) Device Modification is to provide substantial equivalence for Advanced Medical Solutions Limited's Silver Alginate II Dressing, which is substantially equivalent to currently marketed devices intended for wound care. This product is already legally marketed as Silver Alginate II Dressing (unmodified device) and was previously cleared under 510(k) number **K041316**. Both submissions have been made by Advanced Medical Solutions Limited.

Submitted by:-	Advanced Medical Solutions Limited Road Three Winsford Industrial Estate Winsford Cheshire CW7 3PD United Kingdom
Contact:-	Mr. Grahame Somerville Senior Regulatory Affairs Consultant
Telephone:-	+44(0)1606 545569
Fax:-	+44(0)1606 863600
Email:-	grahame.somerville@mediqol.com
Date prepared:-	2nd October 2006-10-02
Classification:-	There is currently no classification for wound and burn dressings.
Common Name:-	Silver Alginate II Dressing
Trade Names:-	Maxsorb Extra Ag Seasorb Ag Invacare Silver Alginate Dressing
Predicate devices:-	K041316 Silver Alginate II Dressing manufactured by Advanced Medical Solutions K013814 Aquacel Ag with hydrofibre manufactured by ConVatec, A division of E.R Squibb and Sons LLC.

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Indications for Use: -

Advanced Medical Solutions Silver Alginate II Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including:

- Post-operative wounds
- Trauma wounds
- Leg Ulcers
- Pressures Ulcers
- Diabetic Ulcers
- Graft and donor sites

Silver Alginate II Dressing is indicated for external use only.

Device Description:-

Silver Alginate II Dressing is a sterile, non woven pad composed of a high G (guluronic acid) calcium alginate, carboxymethylcellulose (CMC) and ionic silver complex (Silver Sodium Hydrogen Zirconium Phosphate), which releases silver ions in the presence of wound fluid. As wound fluid is absorbed the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The silver ions protect the dressing from a broad spectrum of microorganisms over a period of up to *twenty-one (21)* days, based on *in-vitro* testing. . Odour reduction results from the antibacterial effect in the dressing.

Silver Alginate II Dressing is an effective barrier to bacterial penetration. The barrier function of the dressing may help to reduce infection in moderate to heavily exuding partial to full thickness wounds.

The dressing has an off-white appearance and is available in various sizes (5cm x 5cm, 10cm x 10cm, 15cm x 15cm, 10cm x 20cm, 20cm x 30cm flat dressings; 2.7cm x 30cm and 3cm x 44cm flat rope dressings; and 30cm x 2g rope dressings). The flat rope dressings are packaged in pouches and the flat rope and rope dressings are packaged in a blister pack.

Testing:-	The biocompatibility of Advanced Medical Solutions Limited Silver Alginate II Dressing has been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1. Additional *in-vitro* testing and additional microbiological assessment has demonstrated that the key performance characteristics of the dressing are substantially equivalent to the predicate devices.
Statement of:- Substantial Equivalence	The Silver Alginate II Dressing is a non-woven calcium alginate dressing which is substantially equivalent in construction and/or performance to both Anticoat® Calcium Alginate Dressing and Aquacel Ag absorbent antimicrobial wound dressing predicate devices. Comparable absorbency, silver release profile and antimicrobial activity have been demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Advanced Medical Solutions Ltd.
% Mr. G. Grahame Somerville
Senior Regulatory Affairs Consultant
Road Three, Winsford Industrial Estate
Winsford,
Chesire, CW7 3PD United Kingdom

Re: K063173
Trade/Device Name: Silver Alginate II Dressing
Regulation Class: Unclassified
Product Code: FRO
Dated: October 16, 2006
Received: October 19, 2006

Dear Mr. Somerville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

000001

Indications for Use

510(k) Number (if known): K063173/K041316

Device Name: **Silver Alginate II Dressing**

Indications for Use:

Silver Alginate II Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including:

- Post-operative wounds
- Trauma wounds
- Leg Ulcers
- Pressures Ulcers
- Diabetic Ulcers
- Graft and donor sites

Silver Alginate II Dressing is indicated for external use only

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for mxm

Division of General, Restorative, and Neurological Devices

510(k) Number K063173